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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,286	02/03/2006	Yusong Chen	19599.01US1	9742

25541 7590 10/26/2007

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EXAMINER
CARLSON, KAREN C

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
10/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,286	CHEN ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 18-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 18-31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-17 have been cancelled. Claims 18-31 are currently pending and are under examination.

Benefit of priority is set to the filing of PCT/CN04/00138, February 23, 2004. English translated versions of the foreign applications have not been submitted, and it is not known if the art cited below is 102a or 102b art until these foreign documents are in hand.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 18, it is not clear if the cardio myopeptidin polypeptide is being claimed, or a composition comprising the myopeptidin, free amino acids, RNA, and DNA is being claimed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In Claim 18, for example, new matter is introduced because the specification and original claims refer to 75%-90% peptide, and "about 75% to about 90% peptide". Also, the specification and original claims refer to 6%-15% of free amino acid, and not "about 6% to about 15% of free amino acid".

In Claim 25, new matter is introduced because the specification and original claims refer to relative area is 90%-95%, not a "relative areas of about 90% to about 95%".

In Claim 26(d), new matter is introduced because the specification and original claims refer to heating the homogenate to 65-95°C, not "about 65 to about 95°C".

New matter is introduced into Claim 29, wherein the specification and original claims refer to 24-72 hours and not "about 24 to about 72 hours".

Claims 18-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

In Claim 18, there is no structure or function provided for cardio myopeptidin. Therefore, one skilled in the art cannot know the metes and bounds of the claim. Factors to be considered for written description are:

1. level of skill and knowledge in the art: The level of skill of those working in this art is high.

2. partial structure: No full or partial structure is provided for cardio myopeptidin.

Therefore, one skilled in the art cannot identify myopeptidin via structural analysis either by sequence or by amino acid composition.

3. physical and or chemical properties: Chemical and physical properties have been provided, such as isolation from hearts and having a molecular weight of less than 10 kD.

However, without function, one can isolate such a peptide but cannot identify one peptide from the other because no functional characteristics are described in the claim.

4. functional characteristics alone or coupled with a known or disclosed correlation between structure and function: There are no functional or structural characteristics set forth in the claims.

5. method of making the claimed invention. The method of making the claimed myopeptidin is set forth in the specification.

Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to he conclusion that the applicant was in possession of the claimed species of the invention is sufficient (MPEP 2163). In the instant situation, no structural or functional characteristics are set forth in the claims and therefore one skilled in the art could not identify cardio myopeptidin from other cardiac peptides.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 18-31 are rejected under 35 U.S.C. 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over ZL94102798 or ZL94102799 as set forth in the specification at pages 4-5 and 8, for example.

The teachings of these Chinese patents are set forth on pages 4-5, [0009] to [0010]. These patents have not been provided by Applicants, and cannot be obtained by the Examiner. Thus, it is unclear when these patents were published. At [0011], the specification implies that cardio myopeptidin is GMGSP(growth stimulating peptide of the myocardial cells), that is, that the GMGSP described in these patents are obtained by a rough separation purification, the test of activity was simple, and they fail to provide detailed description of the ingredients, use, and efficacy of GMGSP.

The biochemical characteristics of GMGSP and cardio myopeptidin can be compared using the information provided in the specification. At page 6, many characteristics of cardio myopeptidin are set forth, and can be compared to the discussion of GMGSP on pages 4-5.

	Cardio myopeptidin	GMGSP
Origin:	myocardial cells/infant heart	myocardial cells/infant heart
MW:	2 bands: < 10K D	2 bands: 8500 & 10800 D
protease sensitive:	Yes	Yes
stable pH:	3-8	2-9
stable lyophilized:	Yes	Yes
stable freezing:	Yes	4°C/2 yrs; -20 °C for 3 yrs
stable heating:	85 °C for 10 min	95-100 °C for 10 min
HPLC components:	4 peaks (see Figure 1)	4 peaks

The claimed cardio myopeptidin was isolated from heart of non-human infant mammals and is less than 10 kD, as is GMGSP (**Claim 18, 19, 20, 21, 23**). The specific animal of origin is not taught in the specification for GMGSP; however, because the GMGSP was obtained from healthy infant mammals other than human mammals, it is assumed that the GMGSP was obtained from domestic animals such as pigs, cattle, rabbits, or horses (**Claim 22, 24**). Both the GMGSP and myopeptidin displayed 2 bands via isoelectric focusing (MW; **Claim 25**). The GMGSP was placed into a medicament because it's biological activity was assessed (**Claim 31**).

At page 8, [0039], the specification discusses GMGSP and myopeptidin:

Compared with the growth-stimulating peptide of the myocardial cells (GMGSP) disclosed in Chinese patents ZL94102798 and ZL94102799, cardio myopeptidin of the present invention has obviously higher in vitro biological activity. The biological activity of cardio myopeptidin of the present invention is 3-5 times higher than that of the growth-stimulating peptide of the myocardial cells. Comparison data of in vivo drug efficacy shows that cardio myopeptidin poses a favorable impact on the release of myocardial creatine phosphokinase caused by myocardial ischemia-reperfusion injury, activity of lactate dehydrogenase, and contents of free fatty acid and malondialdehyde (MDA).

Taken in total, it appears that cardio myopeptidin is a more purified form of GMGSP, which would be expected to increase the activity of GMGSP. Thus, cardio myopeptidin was known in the prior art as GMGSP. Without understanding if the cardio myopeptidin is in a composition with free amino acids, RNA, and DNA as set forth in the rejection under 112, 2nd paragraph above, it appears that the two proteins are one and the same. Thus, **Claims 18-25 and 31** are anticipated by GMGSP. Alternatively, a more purified preparation of GMGSP renders cardio myopeptidin obvious as claimed. The claimed method of **Claims 26-30** is a general protein purification method; thus, it would appear that GMGSP was made the same way, or alternatively, in much the same way as claimed for making cardio myopeptidin.

There is sufficient evidence that the product disclosed by the reference is Applicants' product, and the burden is shifted to Applicants to distinguish the two. See *In re Best*, 195 USPQ 430 and *Ex Parte Gray* 10 USPQ 2d 1922, 1923.

Applicants should submit English translated versions of Chinese patents ZL94102798 and ZL94102799 that were cited in the specification to overcome this rejection.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cochrane Carlson Ph.D

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER